

Applicants: Kiran K. Chada et al.
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REMARKS

Claims 1-17 are pending in the subject application, of which claims 10-16 have been withdrawn from consideration by the Examiner. By this Amendment, applicants have canceled claims 10-16 without prejudice. Accordingly, claims 1-9 and 17 are currently pending and under examination.

Restriction Requirement

On page 2 of the April 19, 2006 Office Action, the Examiner acknowledged applicant's January 26, 2006 Response but deemed the applicants argument unpersuasive and made the restriction "FINAL".

Applicants have cancelled withdrawn claims 10-16 without prejudice to expedite prosecution of the subject application.

Priority

The Examiner noted that instant application claims priority to US 10/630,423, filed on July 29, 2003, which claims benefit of US Provisional Application 60/398,785, filed on July 29, 2002 and US Provisional Application 60/478,206, filed on July 12, 2003. The Examiner has asserted that the instant application gets priority of U.S. Provisional 60/478,206, filed June 12, 2003, in which applicant has first disclosed the cloning and expression of SFRP5 polypeptide.

Rejection under 35 U.S.C. § 112, first paragraph

-Written Description

On page 3 of the April 19, 2006 Office Action, the Examiner rejected claims 1-9 as failing to comply with the written description requirement. The Examiner alleged that the claims do not require that the sFRP-5 peptide or derivative possess any

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particular conserved structure, or any other disclosed distinguished feature. Thus, the claims are drawn to a genus of polypeptides variant or derivative that is defined by a large number of amino acid substitutions, deletions or insertion modifications.

Applicants' Response

In response, applicants respectfully direct the Examiner to pages 13-16 of the subject specification where the sFRP-5 peptide and gene are described. Specifically, page 13, line 29 to the end of page 14 defines the sFRP-5 pepetide by its sequence! Applicants respectfully request clarification of the Examiner's assertion that the "claims do not require that the sFRP-5 peptide" possess any particular conserved structure.

Applicants respectfully submit that there is no basis to assert that applicants' claims "encompass any peptide, protein or agent that can reduce the amount of adipose tissue." Applicants' claim 1 unambiguously recites use of an "sFRP-5 peptide" which is a defined, specific peptide. Applicants' claim 1 alternatively recite use of "a molecule effective to stimulate expression of the sFRP-5 peptide in the subject."¹ Clearly the claim does not allow use of "any peptide, protein or agent that can reduce the amount of adipose tissue." Furthermore, applicants' claim 7 specifically recites the defined term "sFRP-5 peptide" but is still included in the rejection.

Accordingly, the rejection under 35 U.S.C. § 112, first paragraph, written description, as stated on pages 3-6 of the April 19, 2006 Office Action is not connected to applicants'

¹Applicants point out that sFRP-5 is autoregulatory. See, e.g. page 15, lines 25-28 of the subject application.

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pending claims. Applicants, therefore, respectfully request withdrawal of the rejection on the basis that it does not relate to the specific defined terms of applicants' pending claims.

Rejection under 35 U.S.C. § 112, first paragraph

-Enablement

On pages 6-10 of the April 19, 2006 Office Action, the Examiner rejected claims 1-9 and 17 under 35 U.S.C. § 112, first paragraph, on the basis that the specification allegedly does not reasonably provide enablement for reducing the amount of adipose tissue in a subject by administering to the subject an effective amount of an sFRP-5 peptide of SEQ ID NO:1 or a peptide that has (I) 90% identity to the sequence of SEQ ID NO:1, (ii) 91% identity to the sequence of SEQ ID NO:1, (iii) 92% identity to the sequences of SEQ ID NO:1, (iv) 95% identity to the sequence of SEQ ID NO:1, and (v) 99% identity to the sequence of SEQ ID NO:1.

The Examiner proceeded to then analyze the *In re Wands* factors in the context of applicants' invention. Importantly, when discussing the working example factor, the Examiner acknowledged that applicants have provided a mouse model of their invention. However, the Examiner concluded that a mouse model is insufficient "because the role of sFRPs is still controversial."

Applicants' Response

In response, applicants respectfully submit that an enablement rejection of claims supported by *in vivo* animal studies is suspect.

First, "[A] single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be

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enabled." M.P.E.P. § 2164.02. Indeed, it is readily apparent that the next step after animal model testing of the invention would be human testing. However, it is well settled that patentability does not require human clinical trials. The Court of Appeals has clearly stated that clinical testing and FDA approval are not requirements for patentability. See, e.g. *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). Yet, by dismissing applicants' animal model the Examiner is essentially impermissibly requiring human clinical testing. This is not proper.

Second, the Examiner appears to mischaracterize applicants' animal examples. On page 9 of the April 19, 2006 Office Action, the Examiner alleged that the "ob/ob model or a transgenic mice (figure 7) showing gene expression in adipose tissue is not necessarily predictive of reducing adipose tissue in subjects because the role of sFRPs is still controversial." However, applicants' experiments were not done in the ob/ob mouse model. Rather, applicants' experiments were done in a wild-type mouse model that has been previously shown to have physiological relevance to human disease syndromes. Applicants' example does not simply correlate normal expression in the wild-type mouse with reduction in adipose; applicants' experiment illustrates that an increase in sFRPs to supraphysiological levels in a relevant, wild-type animal, results in a reduction in adiposity.

Third, the April 19, 2006 Office Action provides an illegitimate basis for dismissing applicants' working example. The April 19, 2006 Office Action dismisses applicants' working example on the basis that "the role of sFRPs is still controversial." Applicants respectfully submit that controversy is not a statutorily provided basis for denying applicants a patent for their work. Moreover, the very examples being dismissed are

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clarifying any ambiguity or controversy that existed in the field prior to applicants' invention. Applicants' example clearly illustrates that an increase in sFRP-5 to supraphysiological levels in a relevant, wild-type animal, results in a reduction in adiposity. Applicants respectfully request clarification of what else short of human clinical trials would provide evidence of enablement.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph, enablement.

Rejection under 35 U.S.C. § 112, second paragraph

On page 10 of the April 19, 2006 Office Action, the Examiner rejected claims 1-9 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 1-9, the Examiner alleged that it is unclear what sFRP-5 is because there is no structure recited.

In response, as discussed above, sFRP-5 is defined by its sequence on pages 13-14 of the subject application. Clarification is respectfully requested.

The Examiner also rejected claims 2-6 as allegedly indefinite on the ground that claim 2 encompasses a method of stimulating expression of sFRP-5 with peptide of SEQ ID NO:1 or variants, but the SEQ ID NO:1 is sFRP-5.

In response, applicants wishes to clarify that sFRP-5 is autoregulatory for expression. Thus, as shown in applicants examples, administration of sFRP-5 upregulates the expression of sFRP-5.

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In view of the forgoing explanation, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 102(e)

On page 11 of the April 19, 2006 Office Action, the Examiner rejected claims 1-9 and 17 as allegedly anticipated by Xu et al. (US 2003/0143610, effective priority date 1/8/2002(60/346,523)).

The Examiner alleged that Xu et al. teach administration of a polypeptide SARP of SEQ ID NO:2 which is 100% identical to the polypeptide of SEQ ID NO:1 (Appendix-A) of the instant application for the treatment of metabolic disorders including obesity and diabetes comprising the SARPs polypeptides (see abstract, and claims 9-20). The Examiner stated that Xu et al. do not explicitly teach reduction in an amount of adipose tissue but alleged that the administration of the polypeptide of SEQ ID NO:2 or a variant would inherently achieve the same effect in a subject as being instantly claimed.

In response, as the Examiner is aware, a rejection based on inherent anticipation requires a showing that "the missing descriptive matter is necessarily present in the thing described in the reference." See, e.g. M.P.E.P. § 2112. However, Xu et al. does not actually administer sFRP-5 to a subject. Therefore, in Xu et al. the purported sFRP-5 did not inherently do anything at all. That is, because there was no actual administration of sFRP-5 to a subject in Xu et al., the effect of such administration was not present in Xu et al., and the necessity requirement of an inherency rejection is not satisfied.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 103.

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No fee, other than the enclosed \$510.00 extension of time fee, is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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